

R E M A R K S

Claims 1, 2, 8 to 10, 16 and 20 as set forth in Appendix I of this paper are now pending in this case. Claim 2 has been amended as indicated in the listing of the claims to correct a typographical error. No new matter has been added.

The Examiner rejected those Claims 1, 2, 8 to 10, 16 and 20 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of *Sauer et al.* (CA 2,178,655). The Examiner conceded in this context that the reference failed to identify the heat input employed in the application of the coating which is required in accordance with applicants' invention. He argued, however, that applicants' compositions used the same polymers, carriers, active ingredients and coating steps as taught by *Sauer et al.* and stated "there remains a question as to the CR granules of Sauer being 1) of lower heat input & 2) of different leachability than the instant CR's."<sup>2)</sup>

Applicants respectfully disagree. When applying 35 U.S.C. 103, it is *inter alia* necessary that the reference(s) be considered as a whole, that the reference(s) suggest the desirability and thus the obviousness of making the claimed combination, and that the references be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.<sup>3)</sup> By the same token, in determining obviousness the decisionmaker has to return to the time at which the invention was made.<sup>4)</sup>

A person of ordinary skill in the art who had the teaching of *Sauer et al.* before him but who had no knowledge of applicants' invention could not find any information in the reference which pertained to the heat input employed in the manufacture of the CR granules. The reference not only fails to provide data which are necessary to determine the heat input used in connection with the representative examples which are described on pages 10 et seq. of the reference. The reference also fails to suggest or imply that the heat input is of any moment with regard to the properties of the CR granulates. Before this background, the skilled person who contemplated

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2) Office action page 2, lines 15 to 17.

3) *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

4) E.g. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988), cert. denied, 488 U.S. 825 (1988); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 16 USPQ2d 1923 (Fed. Cir. 1990).

the the teaching of **Sauer et al.** could not reasonably arrive at the conclusion that it would be desirable to determine and/or modify the heat input employed in the preparation of CR granules. At the time applicants made their invention the teaching of **Sauer et al.**, when duly considered as a whole and without the benefit of impermissible hindsight vision afforded by the claimed invention, therefore, clearly failed to suggest the desirability and thus the obviousness of making the combination which is specified in applicants' claims.

As explained in MPEP §2143, three basic criteria have to be met in order to establish a *prima facie* case of obviousness:

- (1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings,
- (2) there must be a reasonable expectation of success, and
- (3) the prior art reference or the combined references must teach or suggest all of the claim limitations.

Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and cannot be based on the applicant's disclosure.<sup>5)</sup>

**Sauer et al.** fail, as conceded by the Examiner, to teach or suggest the heat input limitations of applicants' claims. Accordingly, at least the third of these basic criteria for establishing a *prima facie* case of obviousness is not met where the teaching of **Sauer et al.** and applicants' invention are concerned. It is well settled that obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established.<sup>6)</sup> Moreover, inherency may not be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency.<sup>7)</sup> The Examiner's position that "there remains a question as to the CR granules of Sauer being 1) of lower heat input & 2) of different leachability than the instant CR's" is, in light of the foregoing, clearly not well taken.

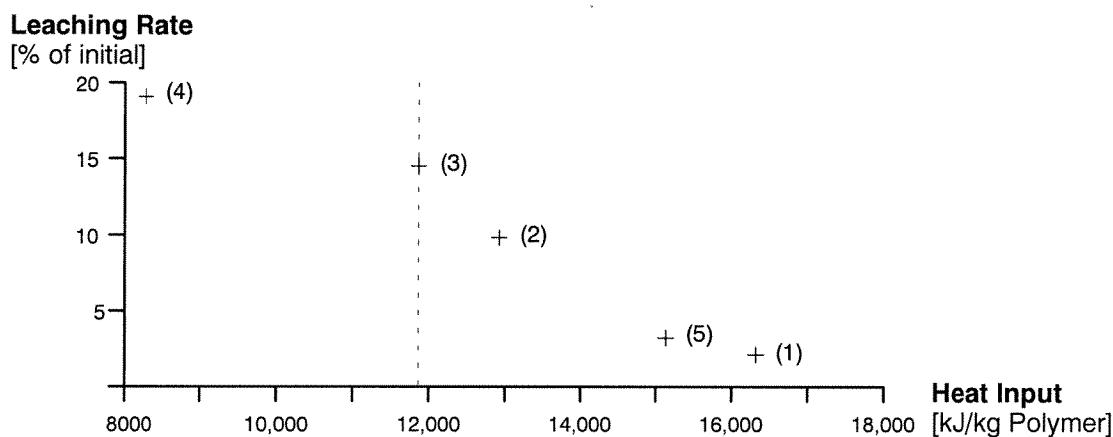
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5) *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

6) *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993).

7) *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

The Examiner also criticized that applicants' data in Table 14b failed to corroborate that the release rate of the active ingredient decreased when the heat input was increased. The Examiner's criticism is not understood. The following figure illustrates the data pertaining to Compound 6 in Samples 1 to 5. In the figure, the leaching rate values given in column 2 of Table 14b are plotted over the heat input values which are given in column 5 of the table. The broken line signifies the lower value of the heat input range specified in applicants' Claims 1 and 9; the sample number is indicated in parenthesis next to the "+" marking the values:



The illustration shows clearly that the leaching rate decreases when the heat input is increased: CR granules which had been prepared applying a heat input of 8,282 kJ/kg polymer leached 19.1% of the initial quantity of the active ingredient over a period of 24 hours at 30°C in 4 liters of water (cf. Sample 4). However, CR granules which had been prepared applying an increased heat input of 12,927 kJ/kg polymer only leached 9.8% of the initial quantity of the active ingredient (cf. Sample 2), and CR granules which had been prepared applying a further increased heat input of 16,322 kJ/kg polymer only leached 2.1% of the initial quantity of the active ingredient (cf. Sample 1). The data set forth in applicants' Table 14b show impressively that the impact of the heat input on the rate at which the active ingredient is leached or released from the CR granule is significant.

The Examiner remarked: "All the material elements & process steps of the instant invention are disclosed."<sup>8)</sup> However, this remark is in error in light of the teaching of *Sauer et al.* when taken as a whole,

8) Office action page 4, line 4.

and in light of the Examiner's concession that **Sauer et al.** fail to disclose any general, let alone specific, information pertaining to the heat input employed in the preparation of the prior art CR granules. The Examiner also stated: "It has not clearly been established by an objective showing of some additional unusual and/or unexpected result that the preparation of the particular CR form, delivery method or target provides a greater level of prior art criticality of expectation as claimed."<sup>9)</sup> To the extent that the Examiner intended to express that applicants have failed to show unexpected results applicants respectfully disagree.

As pointed out in the foregoing, the teaching of **Sauer et al.** contains nothing which suggests or even implies that the heat input which is provided when the coating is applied to form the CR granules has any criticality whatsoever. A person of ordinary skill in the art who had the teaching of **Sauer et al.** before him but who had no knowledge of applicants' invention therefore could reasonably only expect that the heat input had no impact on the properties of the CR granules. Before this background and contrary to any reasonable expectation raised by the teaching of **Sauer et al.**, applicants have found that a modification of the heat input values within a certain range allows a significant reduction of the rate at which the active ingredient is released into the environment. The finding is well corroborated by the data set forth in applicants' Table 14b. The mere fact that it is possible to further control the release rate of the active ingredient by adopting certain heat input values as specified in applicants' claims is, in light of the teaching of **Sauer et al.**, an unexpected result. Again, obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established.<sup>10)</sup> Inherency cannot be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency.<sup>11)</sup>

For the reasons set forth in the foregoing it is respectfully urged that the teaching of **Sauer et al.** is insufficient to establish that applicants' invention as defined in Claims 1, 2, 8 to 10, 16 and 20 is unpatentable under the provisions of Section 103(a). It is

9) Office action page 4, lines 5 to 8.

10) *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993).

11) *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

therefore respectfully requested that the rejection be withdrawn. Favorable action is solicited.